K042872

NOV 2 3 2004

EXHIBIT 2

510(k) Summary

KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60047
Toll Free: 800 323 8029
Tel: 847 / 550 - 6800
Fax: 847 / 550 - 6825
e-mail: info@kavousa.com
Contact: John Franz, President
August 30, 2004

1. Identification of the Device:
   Proprietary-Trade Name: KaVo RONDOflex® plus 360 Handpiece
   Classification Name: Airbrush
   Product Codes KOJ
   Common/Usual Name: Airbrush

2. Equivalent legally marketed device: KaVo Corund Handpiece 2013 (K002708); Velopex Aquacut Fluid Abrasion Unit (K024105) and Sirona Dental Systems Prosmile Air Polisher and Prophylaxis Powder (K033675). The latter two units use water with the airbrush. .

3. Indications for Use (intended use): The KaVo RONDOflex® plus 360 Handpiece is intended for the: preparation for fissure sealing by cleaning, opening, and extending the fissures; creation of micro-mechanical retention for adhesive restorations on enamel and dentine with subsequent acid etch technique; preparation-of small carious defects; removal of deep discolorations in the enamel; cleaning and removal of adhesive residues from bridges, crowns, etc.; and, preparation of adhesive surfaces of brackets.

4. Description of the Device: This submission is for a modification of a device system cleared under K002708, KaVo Corund Handpiece 2013. The modification is in the form of adding dental water to the stream.
   The RONDOflex plus 360 is an air abrasion system in which alumina particles are accelerated to high speed in an air jet in order to remove material from the tooth surface.
   Technical data: RONDOflex plus 360
   Drive pressure: 3.2 - 6.0 bar
   Water pressure: 1.5 ± 1.0 bar Air consumption 5 - 11 l(S.T.P.)/min depending on cannula type
   The pressure set on the turbine drive is automatically increased by 20%, e.g. from 2.8 to 3.2 bar
   Water flow rate: approx. 40 cm3/min
   Have the pressures of your unit which have been set by the manufacturer checked regularly by a service engineer in order to ensure satisfactory operation of the instrument.
   Connection: Can be mounted on all MULTIflex couplings.

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	KaVo Corund Handpiece 2013 (K002708)	Velopex Aquacut Fluid Abrasion Unit (K024105)	Sirona Prosmile Air Polisher and Prophylaxis Powder (K033675)	RONDOflex® plus 360 Handpiece (Modified device)
Indications for use	Preparation for fissure sealing by cleaning, opening, and extending the fissures; creation of micro-mechanical retention for adhesive restorations on enamel and dentine with subsequent acid etch technique; preparation-of small carious defects; removal of deep discolorations in the enamel; cleaning and removal of adhesive residues from bridges, crowns, etc.; and, preparation of adhesive surfaces of brackets.	Preparation for pit and fissure sealants. Removal and restoration of composits (sic) Cavity preparation. Cleaning, polishing, and stain removal	Intended for removing deposits, plaque, and staining on all visible tooth surfaces as well as in fissures and interdental areas. The ProSmile is also intended for the following prophylactic applications: cleaning teeth prior to sealing cleaning teeth prior to fluoridation cleaning teeth prior to bleaching cleaning teeth prior to using bonding materials	SAME as KaVo Corund.
Abrasive Material	27 or 50 μ corundum powder (Aluminum oxide)	29 μ or 53 μ corundum powder (Aluminum oxide) and water	Sirona prophylaxe powder and water	27 and 50 μ corundum powder and water
Sterilization	Autoclave	SAME	SAME	DAME

6. Conclusion: In all important respects, the RONDOflex® plus 360 Handpiece is substantially equivalent to the KaVo Corund Handpiece 2013 (K002708), the Velopex Aquacut Fluid Abrasion Unit (K024105)and the Sirona Dental Systems Prosmile Air Polisher and Prophylaxis Powder (K033675). This conclusion is based on indications for use and internal validation studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2004

KAVO America Corporation
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
PO Box 7007
Deerfield, Illinois 60015

Re: K042872
Trade/Device Name: RONDOflex® plus 360 Handpiece
Regulation Number: 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: KOJ
Dated: October 14, 2004
Received: October 26, 2004

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

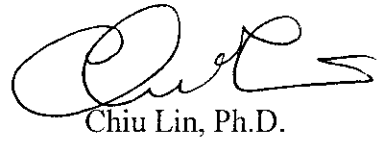
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042872

Indications for Use

510(k) Number (if known):

Device Name: RONDOflex® plus 360 Handpiece

Indications For Use:

The KaVo RONDOflex® plus 360 Handpiece is intended for the:
preparation for fissure sealing by cleaning, opening, and extending the fissures;
creation of micro-mechanical retention for adhesive restorations on enamel and dentine with subsequent acid etch technique;
preparation-of small carious defects;
removal of deep discolorations in the enamel;
cleaning and removal of adhesive residues from bridges, crowns, etc.; and,
preparation of adhesive surfaces of brackets.

Labeling contains the following statement:
CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042872